

REMARKS

Reconsideration is respectfully requested in view of the foregoing amendments in the following remarks.

By this amendment applicants have amended claims 1 and 12 and canceled claims 3 and 7. The amendments made to claims 1 and 12 are fully supported in the as filed application.

The currently pending claims are 1, 2, 4-6 and 8-14.

The objection to the drawing under 37 C.F.R. §1.83(a) is rendered moot in view of the cancellation of claim 7.

Claims 1-3, 6-7 and 12 stand rejected under §102(b) as being anticipated by Gilmer, US 4,723,540. This rejection is respectfully traversed.

Initially, applicants wish to point out to the Examiner that the bone staples disclosed by Gilmer are entirely suitable for the suturing of a sternum. The bone structure of a sternum is generally not very solid, and the sternum is not a thick bone that can withstand the insertion of staples such as those disclosed by Gilmer.

The staples taught by Gilmer have sharp ends that must be inserted by striking. The extremities of the staple itself are adapted to piercing the bone (at most, small pilot holes may be provided before insertion, but striking is necessary to insert the staple). In this regard, see Gilmer Col. 3, lines 39-43. Conversely, staples for the suture of a sternum must be inserted in pre-formed through holes, since the sternum cannot withstand insertion by striking. Moreover, the sharp extremities according to Gilmer are not acceptable when suturing a sternum. Due to the reduced thickness of the sternum, the extremities of the staple are likely to protrude from the back of the sternum into the cavity behind the sternum, unless its arms are very short. (See also the paragraph bridging pages 5 and 6 of the present application.)

The presently claimed invention differs from the staples disclosed by Gilmer in that it is suited for the suturing of a sternum, by the method disclosed in the present application. Furthermore, according to amended claim 1 the legs of the teeth form, with the respective

threaded ends, an acute angle, which is highly advantageous, inasmuch as it allows the staple to be more effectively retained after insertion and tensioning.

Conversely, Gilmer's staple possesses arms which must form right angles with the threaded ends, otherwise insertion by striking, as discussed above, would be impossible. In fact, the insertion of an arm of the staple according to Gilmer must be done along its axis, and the direction of the axes of the two arms must be parallel, since the insertion is simultaneous. Therefore, Gilmer does not disclose the presently claimed invention and, in fact, teaches away from it.

Applicants also wish to point out that the sharp extremities are an essential feature of the staple according to Gilmer, due to the fact that it must pierce the bone upon insertion.

It is respectfully submitted that the §102(b) rejection over Gilmer has been overcome. Accordingly, withdrawal of the rejection of claims 1,2,6 and 12 is respectfully urged.

Claims 9 and 11 stand rejected under 35 USC §102(b) as being anticipated by Burkhardt. This rejection is traversed.

Applicants ask the Examiner to note that the presently claimed forceps possesses means for moving the punching tip, towards the second jaw according to a rectilinear trajectory. The surface of the second jaw is inclined with respect to the axis of the punching tip in order to provide the correct angle of inclination to the hole, corresponding to that of the leg of the staple of claim 1. This is made possible by placing said surface in contact with the back face of the hemisternum (see p. 5, lines 2-18 of the present application) and then closing the jaws.

The device according to Burkhardt differs from the presently claimed forceps at least in that the first jaw (37a) approaches the second jaw (37b) according to a circular trajectory (i.e. about articulation 34). Moreover, the jaws 37a and 37b should have their axes, in correspondence of the tip aligned upon complete closing of the jaws, to produce a straight hole. No means is disclosed by Burkhardt to provide a precise inclination to the hole with respect to a bone surface, as is the case with the presently claimed forceps.

Accordingly, the §102(b) rejection has been overcome and should be withdrawn.

The §103(a) rejection of claims 4 and 8 over Gilmer is traversed. Since claims 4 and 8 depend from independent claim 1, and since claim 1 is deemed to distinguish over Gilmer, then claims 4 and 8 also distinguish thereover.

Claim 5 has been rejected over the combination of Gilmer in view of Peterson et al. This rejection is traversed.

Gilmer discloses a metal staple to be inserted, possibly permanently, into bone tissue to reduce a fracture, equipped with a screw mechanism. A high level of precision and mechanical strength is required. Petersen discloses a fastener of bio-absorbable material used to close wounds in soft body tissues (see figs.6 and 15) of Petersen. It is most likely a device embodying the functions of a suture for use in soft tissues. The combined devices of Gilmer and of Petersen are so different in material, shape, function and possible use that the combination by the Examiner is per se untenable. Withdrawal of the rejection is respectfully requested.

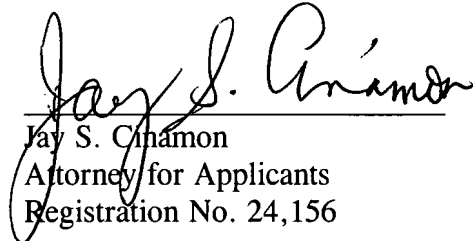
Applicants also wish to point out that the apparatus, for rotating the cylindrical body of the staple, recited in claim 12, comprises a clutch, i.e. (p. 4, lines 12-14 of the present application) a device capable for imparting a predetermined tension when rotating the body. (It is apparent that a clutch is a device capable of automatically interrupting rotation when a predetermined torque, corresponding to a predetermined tension, is reached). This avoids the need for the surgeon to regulate the tension according to his or her subjective evaluation.

The device of Fig. 5 of Gilmer is a simple wrench capable of holding the screwed part of the staple. The surgeon regulates tension by deciding the number of turns to be given (see c. 4, lines 34-41 of Gilmer).

The issuance of a Notice of Allowance is solicited.

Please charge any fees which may be due which have not been submitted herewith to our
Deposit Account No. 01-0035.

Respectfully submitted,


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